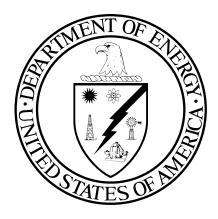
# Regulatory Unit (RU) Readiness Assessment (DOE/EH-0569) RU Response and Corrective Actions



July 1998

Office of Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors

> Richland Operations Office P.O. Box 550 Richland, WA 99352

Approved by:	 		
Date:			

#### **PREFACE**

The Department of Energy's (DOE) Richland Operations Office (RL) issued the TWRS Privatization Request for Proposal (RFP) for Hanford Tank Waste Remediation System (TWRS) Privatization in February 1996. Offerors were requested to submit proposals for the initial processing of the tank waste at Hanford. Some of this radioactive waste has been stored in large underground storage tanks at the Hanford Site since 1944. Currently, approximately 56 million gallons of waste containing approximately 240,000 metric tons of processed chemicals and 250 mega-curies of radionuclides are being stored in 177 tanks. These caustic wastes are in the form of liquids, slurries, saltcakes, and sludges. The wastes stored in the tanks are defined as high-level radioactive waste (10 CFR Part 50, Appendix F) and hazardous waste (Resource Conservation and Recovery Act).

Under the privatization concept, DOE will purchase waste treatment services from a contractor-owned, contractor-operated facility under a fixed-price contract. DOE will provide the waste feedstock to be processed but maintain ownership of the waste. The contractor must: a) provide private financing; b) design the equipment and facility; c) apply for and receive required permits and licenses; d) construct the facility and bring it on-line; e) operate the facility to treat the waste according to DOE specifications; and f) deactivate the facility.

The TWRS Privatization Program is divided into two phases, Phase I and Phase II. Phase I is a proof-of-concept/commercial demonstration-scale effort the objectives of which are to a) demonstrate the technical and business viability of using privatized contractors to treat Hanford tank waste; b) define and maintain adequate levels of radiological, nuclear, process, and occupational safety; c) maintain environmental protection and compliance; and d) substantially reduce life-cycle costs and time required to treat the tank waste. The Phase I effort consists of two parts: Part A and Part B.

Part A consists of a twenty-month development period to establish appropriate and necessary technical, operational, regulatory, business, and financial elements. This will include identification by the TWRS Privatization Contractors and approval by DOE of appropriate safety standards, formulation by the Contractors and approval by DOE of integrated safety management plans, and preparation by the Contractors and evaluation by DOE of initial safety assessments. Of the twenty-month period, sixteen months will be used by the Contractors to develop the Part-A products and four months will be used by DOE to evaluate the products.

Part B consists of a demonstration period to provide tank waste treatment services by one or more of the TWRS Privatization Contractors who successfully complete Part A. Demonstration will address a range of wastes representative of those in the Hanford tanks. Part B will be 10 to 14 years in duration. Within Part B, wastes will be processed during a 5- to 9-year period and will result in treatment of 6 to 13 percent of the Hanford tank waste.

Phase II will be a full-scale production phase in which the remaining tank waste will be processed on a schedule that will accomplish removal from all single-shelled tanks by the year 2018. The objectives of Phase II are to a) implement the lessons learned from Phase I; and b) process all tank waste into forms suitable for final disposal.

A key element of the TWRS Privatization Contracts is DOE regulation of radiological, nuclear, and process safety through the establishment of a specifically chartered, dedicated Regulatory Unit (RU) at RL. This regulation by the RU is authorized by the document entitled Policy for Radiological, Nuclear, and Process Safety Regulation of TWRS

Privatization Contractors (referred to as the Policy) and implemented through the document entitled Memorandum of Agreement for the Execution of Radiological, Nuclear, and Process Safety Regulation of the TWRS Privatization Contractors (referred to as the MOA). The Policy is signed by the Under Secretary of Energy; the Manager, RL; the Assistant Secretary for Environment, Safety and Health (ASEH); and the Assistant Secretary for Environmental Management (ASEM). The MOA is signed by the Manager, RL; the ASEH; and the ASEM. The nature and characteristics of this regulation are also specified in these documents. The MOA details certain interactions among RL, the ASEH, and the ASEM as well as their respective roles and responsibilities for implementation of this regulation.

The authority of the RU to regulate the TWRS Privatization Contractors is derived solely from the terms of the TWRS Privatization Contracts. Its authority to regulate the Contractors on behalf of DOE is derived from the Policy. The nature and scope of this special regulation (in the sense that it is based on terms of a contract rather than formal regulations) is delineated in the MOA, the TWRS Privatization Contracts, and the four documents (listed below), which are incorporated into the Contracts. This special regulation by the RU in no way replaces any legally established external regulatory authority to regulate in accordance with their duly promulgated regulations nor relieves the Contractors from any obligations to comply with such regulations or to be subject to the enforcement practices contained therein.

The Policy, the MOA, the TWRS Privatization Contracts, and the four documents incorporated in the Contracts define the essential elements of the regulatory program, which will be executed by the RU and to which the TWRS Privatization Contractors must conform. The four documents incorporated in the Contracts (and also incorporated in the MOA) are:

Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors, DOE/RL-96-0005,

DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors, DOE/RL-96-0003,

Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors, DOE/RL-96-0006, and

Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization, DOE/RL-96-0004.

In the execution of the regulatory program, the RU will consider not only the relevant approaches and practices of DOE but also those of the Nuclear Regulatory Commission (NRC). The Policy states that

"It is DOE's policy that TWRS privatized contractor activities be regulated in a manner that assures adequate radiological, nuclear, and process safety by application of regulatory concepts and principles consistent with those of the Nuclear Regulatory Commission."

To this end, the RU will interact with the NRC (under the provisions of a memorandum of understanding with the NRC) during development of regulatory guidance and during execution of the regulatory program to ensure implementation of this policy.

All documents issued by the Office of Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors are available to the public through the DOE/RL Public Reading Room at the Washington State University, Tri-Cities Consolidation Information Center, Room 101L, 100 Sprout Road, Richland, Washington, 99352.

# **Executive Summary**

This report presents the corrective actions and responses to all weaknesses identified in DOE/EH-0569, *Assessment of Tank Waste Remediation System-Privatization Regulatory Unit Readiness*, April 1998.

At the request of the Privatization Review Board, the Office of Nuclear and Facility Safety (EH-3) conducted an independent assessment of the Office of Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors (Regulatory Unit) from March 23, 1998 through April 3, 1998. The purpose of the assessment was to determine the readiness of the Regulatory Unit (RU) to regulate Part B of the TWRS Privatization Contracts. The results of the Review Team's independent assessment were transmitted by memorandum from James M. Owendoff, Acting Assistant Secretary for Environmental Management, to John Wagoner, Manager, Richland Operations Office, on May 1, 1998.

The Review Team concluded that the RU met the evaluation criteria of the readiness review and is ready to regulate in Part B provided identified weaknesses are corrected. The weaknesses were categorized by those requiring completion of corrective actions prior to regulating in Part B, and those that could be addressed early in Part B. The transmittal memorandum requested that:

"All actions should be tracked to completion. I would appreciate an initial report as soon as those actions that are to be resolved prior to Part B are completed. The resolution of the remaining corrective actions may be tracked in accordance with the Performance Assessment Division practices."

Upon receipt of the assessment report, the Regulatory Unit immediately began steps to address the identified weaknesses. This response addresses the closure path for all fourteen identified weaknesses. Tables ES-1 and ES-2 list comments and recommendations (C&Rs) of the assessment and provide the current response and closure status for each.

Seven items were identified for action prior to the start of Part B regulation. Of these seven, one C&R has been dispositioned by the RU and is considered closed. This item will be submitted to DOE-RL Performance Assessment Division (PAD) for verification of closure. All other items are on schedule for closure at the earliest possible dates. One of the closure dates extends beyond the start of Part B regulation (assumed to be September 1, 1998) due to unavailability of formal training classes. No negative impact on the ability of the RU to carry out its intended regulatory functions is anticipated.

There were also seven items identified for action early in Part B. One C&R is determined to have been appropriately addressed in the contract and is therefore not accepted by the RU for action. All other identified weaknesses are fully or partially accepted for corrective action by the Regulatory Unit and are on track for closure.

Schedules appropriate to the level and complexity associated with each C&R have been developed, and progress toward completion is being tracked on a weekly basis in the RU Work Plan.

Table ES- 1. Areas to Address Before Regulating in Part B

Title	Comment and Recommendation (C&R)	Response/Corrective Action	Status/Closure Date
Technical Issues Between NRC and DOE Resolution Process Development	The process for resolution of technical issues between NRC and DOE has not matured to the level desired by DOE. Prior to regulating in Part B, the RU should recommend to the parties of the MOA, a process for resolving differences with NRC on technical (e.g., seismic criteria and collocated workers) and other issues that are not clearly addressed in the MOU.	Accepted/Mutually agree with NRC on technical issue resolution process.	Completed/ 4/21/98
Safety Concerns/Allegations Program Coordinator Identification	The RU has not identified and trained an individual to serve as Safety Concerns/Allegations Program Coordinator. This position should be filled and the assigned person trained before regulating in Part B.	Accepted/ Assign individual Complete training	Completed/ 4/98 Scheduled/ 8/98
Technical Qualifications Requirements Establishment	Technical qualification requirements have not been established for the RU staff and, therefore, they have not yet been qualified to DOE Order 360.1, <i>Training</i> . <sup>24</sup> The RU should identify the qualification requirements for RU staff before regulating in Part B, and either complete applicable requirements early in Part B or request exemptions from Order 360.1 as necessary.	Accepted with qualifier/* Finalize TQRs Complete TQP qualification requirements  *(No exemption from DOE Order 360.1 necessary.)	Completed/ 6/04/98 Ongoing/ 11/30/99
Commitment Tracking System Implementation	The RU has not fully implemented its system for tracking commitments. Implementation should be completed before regulating in Part B.	Accepted/ Revise Management Directives (MD) to reflect Work Plan tracking Implement commitment tracking database	Ongoing/ 8/98 Ongoing/ 8/98
Enforcement Lead Coordinator Identification	The RU has not identified and trained an individual to serve as Enforcement Lead Coordinator, but should do so before regulating in Part B.	Partially Accepted/ Identify VCO as Point of Contact Complete training	Completed/ 4/98 Scheduled/ 12/98
Proprietary and Competition Sensitive Information Controls Improvement	Current controls on proprietary and competition sensitive information need improvement. The RU plans to upgrade its guidance in this area and should do so before regulating in Part B.	Accepted/ Revise MD 2.1, Information Management Complete staff training	Ongoing/ 8/98 Scheduled/ 8/98
Planned Reorganization Completion	The planned reorganization should be completed before regulating in Part B.	Accepted. Implement reorganization Revise MOA & other documents to reflect reorganization.	Completed/ 5/4/98 Ongoing/ 7/98

Table ES- 2. Areas to Address Early in Part B Regulation

Title	Comment and Recommendation (C&R)	Response/Corrective Action	Status/Closure Date
Fill Open Federal Positions	Very early in Part B, the RU needs to fill open federal staff positions with personnel having expertise in the areas of process safety management and vitrification.	Accepted/ Bring two identified candidates on board Bring Vitrification expert on board Complete process safety management training	Ongoing/ TBD Ongoing/ TBD Scheduled/ 4/99
Back-fit Process Directive and Handbook Development	The RU should develop a directive and handbook on its back-fit process early in Part B.	Accepted/Develop MD & Handbook	Ongoing/ 12/98
Schedule Adjustments Mechanism Identification	The RU review schedules are tied to DOE's contract milestones, exposing the RU to pressure to complete regulatory evaluations on a fixed schedule. Early in Part B, the RU should pursue, with the parties of the MOA, a mechanism that allows adjustments to the schedule if necessary for RU reasons.	Not Accepted*/N/A  *TWRS-P Contract provides RO with review schedule flexibility and Contractor with remedy, if warranted	Completed/ N/A
Contract and Contract Attachment Inconsistencies	There are inconsistencies among the contracts and the contract attachments. Early in Part B, the RU and Contracting Officer should improve their interface to ensure modifications affecting RU responsibilities are appropriately made.	Partially Accepted/Revise J Documents to Achieve consistency with balance of Contract	Ongoing/ 8/98
Consistent PSAR Guidance Development	The Contractors have selected different approaches to their PSARs. If two contractors are selected for Part B, the RU faces a challenge of developing consistent guidance for reviewing the two different PSARs. This guidance should be initiated early in Part B.	Partially Accepted/Initiate guidance Development (Note: two contractor Scenario/concern no longer relevant)	Completed/ 6/98
Pre-construction Inspection Procedures (Modules) Development	Development of pre-construction inspection procedures (modules) should be elevated in priority. Resources should be allocated to ensure that inspection modules are available in sufficient time to train staff, advise stakeholders, and support all pre-construction and limited construction authorization inspection activities early in Part B.	Accepted/ Complete identified pre-construction Inspection Modules (procedures) Advise stakeholders Complete Training	Ongoing/ 9/98 Planned/ 9/98 Planned/ Just-in-time Training
Clarification of RU Role in Land Lease	The RU role in the land lease is unclear and should be clarified early in Part B. The RU should review the actual land lease, when it becomes available, to determine if any inappropriate transfers of RU obligations are apparent in the document.	Accepted/ Review proposed Part B land lease Review executed lease	Completed/ 6/98 Planned/ TBD

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#### 1.0 Introduction

#### 1.1 Background

This report presents the corrective actions and responses to the weaknesses identified in the *Assessment of Tank Waste Remediation System-Privatization Regulatory Unit Readiness*, DOE/EH-0569, April 1998.

The assessment report provided the results of an independent review to determine the readiness of the Regulatory Unit (RU) of the U.S. Department of Energy's (DOE) Richland Operations Office (RL) to regulate Part B of the Tank Waste Remediation System Privatization (TWRS-P) Contracts. The review was conducted from March 23 to April 3, 1998, by the Office of Environment, Safety and Health (EH). The readiness review was performed by a team of regulatory experts under the direction of the Office of Nuclear and Facility Safety (EH-3). Using requirements and recommendations from seven International Atomic Energy Agency (IAEA) publications, including the Code and Safety Guides for a regulatory body responsible for safety of nuclear facilities, the Team developed specific evaluation criteria appropriate to the responsibilities of the RU during Part B. To facilitate the readiness review, the evaluation criteria were categorized into seven topical areas – three of which addressed the readiness of the RU's organization and resources, and four that addressed the readiness of the RU's regulatory framework.

The process of the assessment was clearly expressed and well understood. The assessment process not only examined the implementation of the TWRS-P Policy<sup>1</sup> and MOA<sup>2</sup> but also subjected, to a degree, the program described in the Policy and the MOA to examination in comparison to authoritative publications and Review Team experience in establishing a safety regulatory program. The assessment should provide increased confidence that the TWRS-P regulatory program is founded on proven and accepted regulatory principles.

The Team concluded that the RU met the evaluation criteria of the readiness review and is ready to regulate in Part B provided identified weaknesses are corrected. The selected evaluation criteria were categorized into seven topical areas – management and organization, interfaces, staffing, technical standards, authorization process, document reviews, and inspection and enforcement. The seven topical - areas were assessed with consideration for the five principles of good regulation, as articulated by the NRC and endorsed by the RU. These principles are independence, openness, efficiency, clarity, and reliability.

#### 1.2 Purpose

The purpose of this report is to respond to the Review Team finding that the criteria have been met with the exception of identified weaknesses. The weaknesses in each topical area were categorized by those requiring completion of corrective actions prior to regulating in Part B and those that could be addressed early in Part B. The required actions during Part B are substantially greater for the two contractor case over the one contractor case, primarily due to the added volume of reviews and the need to maintain a high degree of consistency between both contractors.

# Areas to Address Before Regulating in Part B – Comments and Recommendations

• Technical Issues Between NRC and DOE Resolution Process - The process for resolution of technical issues between NRC and DOE has not matured to the level desired by DOE. Prior to regulating in Part B, the RU should recommend to the parties of the MOA, a process for resolving differences with

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<sup>&</sup>lt;sup>1</sup> DOE/RL 96-25, Policy for Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors, July 3, 1996

<sup>&</sup>lt;sup>2</sup> DOE/RL 96-26, Memorandum of Agreement for the Execution of Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors, July 3, 1996

- NRC on technical (e.g., seismic criteria and collocated workers) and other issues that are not clearly addressed in the MOU.
- Safety Concerns/Allegations Program Coordinator The RU has not identified and trained an individual to serve as Safety Concerns/Allegations Program Coordinator. This position should be filled and the assigned person trained before regulating in Part B.
- Technical Qualifications Requirements Technical qualification requirements have not been established for the RU staff and, therefore, they have not yet been qualified to DOE Order 360.1, Training.<sup>24</sup> The RU should identify the qualification requirements for RU staff before regulating in Part B, and either complete applicable requirements early in Part B or request exemptions from Order 360.1 as necessary.
- *Commitment Tracking System* The RU has not fully implemented its system for tracking commitments. Implementation should be completed before regulating in Part B.
- Enforcement Lead Coordinator The RU has not identified and trained an individual to serve as Enforcement Lead Coordinator, but should do so before regulating in Part B.
- Proprietary and Competition Sensitive Information Controls Current controls on proprietary and competition sensitive information need improvement. The RU plans to upgrade its guidance in this area and should do so before regulating in Part B.
- *Planned Reorganization Completion* The planned reorganization should be completed before regulating in Part B.

# Areas to Address Early in Part B Regulation - Comments and Recommendations

- Fill Open Federal Positions Very early in Part B, the RU needs to fill open federal staff positions with personnel having expertise in the areas of process safety management and vitrification.
- Backfit Process Directive and Handbook The RU should develop a directive and handbook on its backfit process early in Part B.
- Schedule Adjustments Mechanism The RU review schedules are tied to DOE's contract milestones, exposing the RU to pressure to complete regulatory evaluations on a fixed schedule. Early in Part B, the RU should pursue, with the parties of the MOA, a mechanism that allows adjustments to the schedule if necessary for RU reasons.
- Contract and Contract Attachment Inconsistencies There are inconsistencies among the contracts and the contract attachments. Early in Part B, the RU and Contracting Officer should improve their interface to ensure modifications affecting RU responsibilities are appropriately made.
- Consistent PSAR Guidance The Contractors have selected different approaches to their PSARs. If two contractors are selected for Part B, the RU faces a challenge of developing consistent guidance for reviewing the two different PSARs. This guidance should be initiated early in Part B.
- *Pre-construction Inspection Procedures (Modules) Development* Development of pre-construction inspection procedures (modules) should be elevated in priority. Resources should be allocated to ensure that inspection modules are available in sufficient time to train staff, advise stakeholders, and support all pre-construction and limited construction authorization inspection activities early in Part B.
- Clarification of RU Role in Land Lease The RU role in the land lease is unclear and should be clarified early in Part B. The RU should review the actual land lease, when it becomes available, to determine if any inappropriate transfers of RU obligations are apparent in the document.

#### 1.3 Comment & Recommendation (C&R) Resolution Approach

Upon receipt of the EH-3 assessment, three individuals reviewed the report and compiled initial

impressions and recommendations. In a parallel effort, the RU Assessment Coordinator, assigned by the RO, developed an overall administrative process to address all C&Rs from the assessment and ensure that each is tracked to closure. The primary elements of the process are outlined below.

#### Administrative Process Elements

- Development of general plan and schedule for preparation of response and inclusion in the RU Work Plan
- Identification of each C&R and entry into the RU Work Plan
- Assignment of each C&R to appropriate RU staff for evaluation and preliminary disposition
- Development of preliminary disposition for each C&R, including consideration of the following:
  - > Statement of C&R (with reference to source)
  - > Statement of Work to disposition each C&R
  - ➤ Identification of tasks and deliverables
  - ➤ Identification of resources and schedules
  - ➤ Integration of disposition work activities into RU Work Plan
- Confirm agreement between RU and the Review Team regarding substance of each C&R
- RO determination of disposition of each C&R
- Confirm the Work Plan is responsive to each C&R
- Formally dispose of C&Rs not accepted by the RU
- Prepare final report on the response and corrective actions
- Track each C&R to closure
- DOE-RL/PAD verification that each C&R is closed (per Owendoff to Wagoner memo of May 1, 1998).

Because of the uncertainties associated with determining the exact date for signing of the Part B contract, the RU has assumed the earliest date for the Regulatory Unit to perform a regulatory function as being September 1, 1998. This meets the intent of the Section 2.0 Comments and Recommendations required to be complete prior to *regulating* in Part B.

# 2.0 Areas to Address Before Regulating in Part B

#### 2.1 Technical Issues Between NRC and DOE Resolution Process Development

**Comment and Recommendation:** "The process for resolution of technical issues between NRC and DOE has not matured to the level desired by DOE. Prior to regulating in Part B, the RU should recommend to the parties of the MOA, a process for resolving differences with NRC on technical (e.g., seismic criteria and collocated workers) and other issues that are not clearly addressed in the MOU."

#### **Designated RU Contact:**

D. Clark Gibbs

**Disposition of C&R:** The suggestion that there is a need to reopen negotiations on the MOU does not take into account the history of the existing document. Provision for just such a technical resolution process was removed from the draft MOU at the insistence of the NRC.

While there are issues under discussion with NRC, they are far from presenting significant obstacles to the continuation of Part B. These issues (i.e., seismic and location of the site boundary) are not technical issues that are unique to the TWRS-P Contractor. Rather, they represent technical issues that must be resolved for other hazardous activities at the site.

On April 21, 1998, a meeting was held between the NRC and the Regulatory Unit. Elizabeth Ten Eyck, Director of the Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and

Safeguards represented the Nuclear Regulatory Commission and Dr. D. Clark Gibbs spoke for the Regulatory Unit. Several topics were discussed at the meeting including that of joint development of issue papers. Ms. Ten Eyck proposed the following approach to issue resolution:

"Regarding our discussion of the need to coordinate papers with TWRS on policy issues that NRC staff need timely Commission resolution to be responsive to TWRS needs, we propose the following approach. On such topics NRC staff will develop Issue Papers which we will provide to TWRS, for your timely review and comment, to ensure that NRC staff have accurately presented the TWRS position. If we cannot reach agreement on the content of the Issue Paper, we will forward your comments as an attachment to the Issue Paper. NRC staff will then independently develop a cover Commission Paper which will be forwarded to the Commission with the subject Issue Paper attached."

This proposal from Ms. Ten Eyck is accepted as a process for resolving differences with the NRC on technical issues. It also constitutes closure of the C & R.

Disposition of any portion of C&R not accepted by the RU:

Not applicable.

**Present status of C&R:** The RU considers this item to be closed. DOE-RL/PAD will be requested to verify closure.

#### 2.2 Safety Concerns/Allegations Program Coordinator Identification

**Comment and Recommendation:** "The RU has not identified and trained an individual to serve as Safety Concerns/Allegations Program Coordinator. This position should be filled and the assigned person trained before regulating in Part B."

# **Designated RU Contact:**

Patrick P. Carier/Chung-King Liu

**Disposition of C&R:** The RU has recently reorganized to more effectively conduct operations during Part B of the contract. As a result, the Verification and Confirmation Official (VCO) has been designated as the individual responsible for implementation of the safety concerns and safety allegations programs.

The RO assigned an individual to be the Safety Concerns/Allegations Program Coordinator, as a collateral duty, in April 1998. This assignment has been reflected in the individual's position description. This individual will receive direction for managing the safety concerns and safety allegation program directly from the VCO.

In reviewing Management Directive 5.1, "Management of Safety Concerns and Safety Allegations," the RU identified that the Safety Concerns/Allegations Program Coordinator (SCAPC) needed to be knowledgeable of the subjects of freedom of information and privacy. Therefore, the RU has scheduled the SCAPC to attend a "Freedom of Information and Privacy Act Workshop" in August 1998. The RU also developed a qualification card for the SCAPC.

**Disposition of any portion of C&R not accepted by the RU:**Not applicable

**Present status of C&R:** The SCAPC has been identified and appropriate training has been scheduled (next available class - August 1998).

# 2.3 Technical Qualifications Requirements Establishment

**Comment and Recommendation:** "Technical qualification requirements have not been established for the RU staff and, therefore, they have not yet been qualified to DOE Order 360.1, *Training*. The RU should identify the qualification requirements for RU staff before regulating in Part B, and either complete applicable requirements early in Part B or request exemptions from Order 360.1 as necessary."

#### **Designated RU Contact:**

Neal K. Hunemuller

**Disposition of C&R:** Although the readiness review concluded that the existing RU staff have excellent credentials and experience, the Team recommended that certification through a formal process would further demonstrate capabilities in the regulation of the privatized contractors. The assessment report recognized that the RU planned to develop Individual Development Plans (IDPs), Training Requirements Matrices (TRMs), and Technical Qualification Program (TQP) qualification cards for the RU Federal core staff. The report also recognized that the RU planned to transmit this information to the RL Office of Training by the end of May, and that RU Federal technical employees would complete their qualification cards within eighteen months from that transmittal.

The RU developed IDPs, TRMs, and TQP qualification cards, as applicable, for the RU Federal core staff. The IDPs, TRMs, and TQP qualification cards were transmitted to the RL Office of Training on June 4, 1998. Three RU Federal employees have completed their TQP qualification requirements. The nine other RU Federal employees participating in the TQP are, on average, 79% complete. These employees are scheduled in the RU Work Plan to complete their TQP qualification requirements by November 30, 1999. Any RU new hires required to be in the TQP will complete the program within eighteen months of their hire date. Specific TQP competencies were considered complete if they were 1) met by experience-, education-, or training-based equivalency or 2) exempted because they were not required to perform the duties and responsibilities of the employee's position.

Disposition of any portion of C&R not accepted by the RU:

Not applicable

**Present status of C&R:** Technical qualifications have been identified for the RU staff, and progress on applicable requirements is on schedule and within the requirements of DOE Order 360.1. No exemption is necessary.

#### 2.4 Commitment Tracking System Implementation

**Comment and Recommendation:** "The RU has not fully implemented its system for tracking commitments. Implementation should be completed before regulating in Part B."

#### **Designated RU Contact:**

Patrick P. Carier

**Disposition of C&R:** The RU currently has a system for tracking commitments made by the Contractor to resolve issues raised by the RU during the Standards Approval and the Initial Safety Assessment regulatory actions. The Contractor documents submitted in connection with these regulatory actions are being revised to incorporate the commitments currently being tracked by the RU. Satisfactory completion of these document revisions is a condition for approving the Contractor's documents. Once these revisions are satisfactorily completed, the Contractor's documents will become the authorization basis that fully reflects commitments made by the Contractor. Accordingly, there will be no need to track these specific commitments further.

Following approval of the Contractor's authorization basis documents, there will be circumstances where the Contractor will make commitments in addition to those currently reflected in the authorization basis. The RU is developing the administrative process to ensure that these commitments are identified and tracked. This administrative process will be described in Management Directive 2.3, "Authorization Basis and Commitment Management," and the related Handbook. The Management Directive and Handbook will be based, in part, on RL/REG-97-13, "Regulatory Unit Position on Contractor-Initiated Changes to the Authorization Basis." The RU is developing a database that will facilitate the process described in Management Directive 2.3. Completion of the Management Directive, Handbook, and associated database is targeted for August 31, 1998.

The RU currently tracks RU work assignments and actions through the RU Work Plan. This system is

being upgraded to address the tracking of actions that are the responsibility of the RU. The action tracking system is being integrated with the information management administrative process to ensure that required actions are identified, appropriately staffed and scheduled, and tracked. A database application is being developed to implement the action tracking system. Management Directives 2.1, "Information Management," and 2.2, "Database Management Systems," and associated Handbooks are being revised to address the administrative controls related to action tracking and the interface with the information management system. Completion of the Management Directive and Handbook revisions is targeted for August 31, 1998.

**Disposition of any portion of C&R not accepted by the RU:** Not applicable.

**Present status of C&R:** The existing RU work assignments and action tracking system are being upgraded. Appropriate procedures will be in place with the start of Part B regulation. The existing Contractor commitment tracking data base is being revised and upgraded to address not only the issues identified in the Standards Approval Package regulatory action, but also the needs of the RU with respect to Authorization Basis commitments. This phase of the work is expected to be completed just prior to the start of Part B, well in advance of the need.

#### 2.5 Enforcement Lead Coordinator Identification

**Comment and Recommendation:** "The RU has not identified and trained an individual to serve as Enforcement Lead Coordinator, but should do so before regulating in Part B."

## **Designated RU Contact:**

Patrick P. Carier

Disposition of C&R: The RU has recently reorganized to more effectively conduct operations during Part B of the contract. As a result, the Verification and Confirmation Official (VCO) has been designated as the individual responsible for enforcement action coordination. This assignment has been included as a collateral duty in the VCO's position description. The VCO is responsible for providing accurate and timely information to the DOE Headquarters EH enforcement staff for TWRS-P enforcement issues. Recent discussions have been held between the RU and the Price Anderson Amendment Act (PAAA) coordinator for the Richland Field (RL) Office. Following these discussions, the RU has concluded that, whenever possible, the existing RL process will be used for handling future enforcement actions. This process is outlined in a memorandum dated September 29, 1997 (from P. W. Kruger, Director Office of Environment, Safety and Health to all RL Assistant Managers). This memorandum establishes an RL PAAA coordinator and outlines the policy that should be used to disposition potential PAAA violations at the Hanford site. The RL PAAA coordinator may be used to coordinate information exchange between the RU and DOE HQ individuals responsible for the enforcement program.

**Disposition of any portion of C&R not accepted by the RU:** Training seminars for the PAAA coordinator are conducted on a yearly basis. The VCO will be attending the next scheduled training seminar in December 1998. In addition, to better understand the needs of the HQ EH Enforcement staff, the VCO will also spend some on-site training time. This training will be accomplished prior to the end of the 1998 calendar year. Non-acceptance of this portion of the C&R is a function of timing only.

**Present status of C&R:** The Enforcement Lead Coordinator has been identified and appropriate training has been scheduled (next available class - December 1998).

#### 2.6 Proprietary and Competition Sensitive Information Controls Improvement

Comment and Recommendation: "Current controls on proprietary and competition sensitive

information need improvement. The RU plans to upgrade its guidance in this area and should do so before regulating in Part B."

# **Designated RU Contact:**

Patrick P. Carier

**Disposition of C&R:** The RU agrees that the guidance provided in the Management Directive 2.1, "Information Management," for RU-generated documents that contain proprietary and competition-sensitive information, needs to be strengthened. The management directive addresses how the RU manages Protected Information. Protected Information is defined as "Proprietary or other information established as warranting special handling to protect trade secrets or competition-sensitive information as referenced in DEAR 952.227-75, 10CFR2.790, and DOE Order 1700.1." The current version of the directive provides general guidance for labeling Protected Information. However, this guidance is not specific to correspondence generated by the Regulatory Unit.

To address this issue, Management Directive 2.1 will be modified. A new section will be added in Part V of the Handbook entitled "Handling Protected Information." This new section will specifically address marking requirements for outgoing (RU generated) information. This new section will amplify the following guidance:

- The originator of the document will be responsible for identifying the information that is considered Protected Information.
- Protected Information that contains Proprietary Data, as defined in DEAR 952.227–75, "Rights in Technical Data–Long Form," February 12, 1997, will contain the "Limited Rights Legend" as provided in Exhibit V-5 of the handbook. This legend identifies the document as containing proprietary data.
- Each page of the document that contains the Protected Information/Proprietary Data will have a header and footer that will label the page as containing Protected Information/Proprietary Data. Exhibit V-4 of Handbook 2.1 provides an example of the type of marking that will be used.
- Within each page of the document the text that contains the Protected Information/Proprietary Data will be shaded in order to further identify the information needing protection.
- Outgoing documents (e.g. cover letters or memoranda) that do not themselves contain Protected Information but are used to transmit one or more documents containing Protected Information, will be marked to indicate that Protected Information is contained in the documents. Additionally, the following marking will be placed at the bottom of the transmittal document cover sheet:

"This document transmits the enclosed Protected Information. When separated from enclosures this document is not protected."

These changes will be incorporated as part of an on-going revision to Management Directive 2.1. This revision is scheduled for completion in August 1998. Training on the revised Management Directive will be provided by the end of August 1998. This training will emphasize the changes made to the procedure. In particular, the training will address changes made to internally-generated Protected Information.

**Disposition of any portion of C&R not accepted by the RU:**Not applicable

**Present status of C&R:** Formal changes to the RU Management Directives are well underway and planned completion is scheduled prior to the assumed date for regulation in Part B.

# 2.7 Planned Reorganization Completion

**Comment and Recommendation:** "The planned reorganization should be completed before regulating in Part B."

#### **Designated RU Contact:**

Neal K. Hunemuller

**Disposition of C&R:** The assessment report recognized that the RU planned to reorganize to become more compatible with its planned activities in Part B. The RU has already begun to work under the new organizational structure, but documentation needs to be revised to formalize the reorganization. Actions to complete formalization of the reorganization have been incorporated into the RU Work Plan.

Throughout Part A, the RU was, of necessity, operating functionally in a structure and manner not consistent with the formal construct as shown in the governing document for Regulatory Program implementation, the Memorandum of Agreement (MOA), DOE/RL-96-26, Revision 0. Consistent with Part A activities, the RU organizational concept included two Project Management teams. The reorganization recognizes that Activities Authorization is the role of the Project Manager, and carries the existing concept forward (in a single Part B contractor environment) under the Project Management Group. The Requirements and Standards Group as provided for in the MOA has been abolished and replaced by the Safety Review Group. Safety review is clearly descriptive of a major RU activity, while standards and requirements is more closely associated with the privatized contractor responsibility. Consistent with the MOA, the reorganization retains the Verification and Confirmation Group as a necessary third component. Each of the three technical Regulatory Groups is headed by a Group Official. The new structure also includes the Policy and Training Advisor and the Regulatory Process Administrator as positions supporting all three Regulatory Groups and reporting directly to the Regulatory Official.

The reorganization establishes the Project Management Official as the Contractor's principal point-of-contact with the RU. However, this is a minor change as the Contractor's principal point-of-contact to date has been the Review Team Leader whose role was very similar to the proposed role of the Project Management Official.

The reorganization reflects the targeted full-time equivalent ceiling of 17 federal employees rather than the 20 shown in the initial Memorandum of Agreement, DOE/RL-96-26, Revision 0. Support for privatization objectives and consistency with NRC concepts and principles is improved by the change. The proposed change more closely approximates the NRC's organization. The change is consistent with the implementing principles of efficiency and reliability and with just one Part B contractor.

The RU incorporated a list of "RU Reorganization Tasks" into the Regulatory Unit Work Plan. The initial target for their completion is July 30, 1998. However, changes to the Memorandum of Agreement (DOE/RL-96-26) are subject to review and approval by representatives of the signatories: the Manager, DOE Richland Operations Office, the Assistant Secretary for Environment, Safety, and Health, and the Assistant Secretary for Environmental Management. The RU does not anticipate any objections to the reorganization and intends to proceed with revising the remaining documentation. However, the RU also recognizes that the final completion date may be later than July 30, 1998.

**Disposition of any portion of C&R not accepted by the RU:** Not applicable.

**Present status of C&R:** The RO implemented the reorganization on May 4, 1998. Revisions to all affected documents are scheduled for completion prior to the start of Part B.

# 3.0 Areas to Address Early in Part B Regulation

Several of the comments in this section of the EH-3 assessment report do not appear to recognize the framework of the regulatory environment established in the Governing Documents and the contracts. Underlying the concern regarding the ability of the RU to meet its review obligations later in Part B is a tacit criterion of "consistency" which exceeds the Regulatory Policy Objectives (*Policy for Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors, DOE/RL-96-25, July 3, 1996, Section 3.0).* The incorporation of the TWRS-P regulatory environment as an evolving one within the context of an uncompleted, competitive procurement action makes concerns over consistency nearly moot. The safety triad\* can be satisfied in many different and equally acceptable ways. The role of the RU is to confirm that each contractor has found one of them, not to steer the contractor toward any particular approach.

Commitments by DOE to support innovation in technical process and tailoring in the selection of standards from among all available standards demands that the RU be prepared to review whatever standards-based safety management scheme the contractor has devised. In this regulatory framework, the criterion of "consistency" is only applicable in terms of whether each contractor's proposed approach is internally self-consistent. The RU must take great care to avoid dictating to the contractor what internal features of its Safety Management System program are non-discretionary, as the RU has no authority under the contract to do so. Rather, the basis for the adequacy of the contractor's approach is the contractor's justification, and the RU's confirmation, that the proposed set will satisfy the triad. If the contractor has an acceptable approach, additional requirements cannot be imposed simply because other approaches may have been taken elsewhere.

# 3.1 Fill Open Federal Positions

**Comment and Recommendation:** "Very early in Part B, the RU needs to fill open federal staff positions with personnel having expertise in the areas of process safety management and vitrification. If two contractors are selected for Part B, the RU core federal staff should be increased by approximately another five full-time employees to handle the increased workload."

## **Designated RU Contact:**

Neal K. Hunemuller

**Disposition of C&R:** The assessment report stated that RU staffing during the review period was 13 of 17 allocated full-time employees. However, the report did not recognize that as of the end of the assessment period, the RU had selected personnel to fill three of the four vacant positions, and one individual has subsequently come on board. Neither the qualification requirements nor the ranking factors for these three positions specifically included process safety management. This was due to the fact that Dr. Chung King Liu was already filling the position identified for the process safety management expert. The remaining vacant position was, and still is, reserved for a vitrification expert.

The RU intends to augment staff expertise in the area of process safety management through training of the core staff and continuing use of expert consultants. Specific training requirements were identified in Dr. Liu's Training Requirements Matrix, Individual Development Plan, and Technical Qualification Program Qualification Card, so that he could serve in the capacity of an expert with respect to process safety management. The RU may also pursue rotational or detail assignment opportunities for Dr. Liu to increase his experience in process safety management. Additionally, the RU plans to provide familiarity-level training to all of the core staff. For example, the RU has obtained the two-day course, "Process Safety Management and Risk Management Plans," from H&R Technical Associates, a consulting firm already supporting the RU.

RL/REG-98-15

\*

<sup>\*</sup> Safety triad: The concept that adequate safety is achieved through the combination of three essential elements: 1) conformance with the DOE Top-Level Safety Standards and Principles; 2) Compliance with applicable Federal, State, and local laws and regulations; 3) Adherence to the Process for Establishing Safety Standards and Requirements. "Adequate" does not mean "at the limit" or "just barely enough." Rather, it is defined by solid requirements and a rigorous process the contractor must follow.

Dr. Liu is scheduled to attend the following process safety management-related training:

Course No.	Provider	Course Title	Hrs	Start Date
PSI 108	Process Safety Institute	Hazard Evaluation: Consequence Analysis Methods	40	06/15/98
PSI 108	Process Safety Institute	Process Safety Management: Compliance Auditing for OSHA PSM and EPA RMP	24	07/15/98
P-102	NRC	Probability and Statistics for PRA	40	11/16/98
P-200	NRC	System Modeling Techniques for PRA	32	01/12/99
P-201	NRC	Human Reliability Assessment	24	02/09/99
P-105	NRC	PRA Basics for Regulatory Application	24	04/13/99

Table 3.1- 1. Process Safety Management Training for Dr. Liu

Additionally, all RU core staff are scheduled to attend the following process safety management-related training:

Course No.	Provider	Course Title	Hrs	Start Date
To Be Determined	H&R Technical Associates	Process Safety Management and Risk Management Plans	16	9/01/98

Table 3.1- 2. Process Safety Management Training for Regulatory Unit Staff.

Aggressive efforts to fill the position of vitrification expert have resulted in the recent identification of a qualified candidate. The paperwork associated with the Excepted Service employee approval process is underway.

Two contractors will not be selected for Part B, therefore the recommendation to increase the RU federal core staff by approximately another five full-time employees is not applicable and will not be addressed further.

Disposition of any portion of C&R not accepted by the RU:

Not applicable.

**Present status of C&R:** Selection of two additional staff personnel has been made pending DOE HQ Executive Resources Board approval. The RU has recently identified a qualified candidate for the position of vitrification expert. The Excepted Service employee approval process is underway. An individual from the RU has been identified to receive comprehensive process safety management (PSM) training with general PSM training being provided to all Federal technical staff. No further increase in the number of staff is anticipated since only one contractor will proceed to Part B.

#### 3.2 Backfit Process Directive and Handbook Development

**Comment and Recommendation:** "The RU should develop a directive and handbook on its backfit process early in Part B."

## **Designated RU Contact:**

Patrick P. Carier

**Disposition of C&R:** The RU is currently in the process of developing guidance for implementing the TWRS-P back-fit process. As a first step in the development process, the RU has issued RL/REG-98-14, "Regulatory Unit Position on New Safety Information and Back-fits," for comment. RL/REG-98-14 describes the RU position with regard to evaluating the need for new regulatory requirements and implementing back-fits under the unique circumstances of the TWRS-P regulatory program. The positions described in RL/REG-98-14 are consistent with the MOA (*Memorandum of Agreement for the Execution of Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors*, Revision 0, DOE/RL-96-26, July 3, 1996) and the Regulatory Process document (*DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, DOE/RL-96-0003; Revision 0, February 1996) and will establish the basis for a sufficiently defined and deliberate back-fit process.

RL/REG-98-14 distinguishes regulatory actions taken to ensure adequate safety is achieved from those being considered as potential safety enhancements. The positions described in RL/REG-98-14 include process attributes such as cost-benefit analysis; Contractor involvement; an opportunity for public input to the decision-making process; and independent review by DOE EH. These attributes are applied as appropriate, depending on the basis for taking regulatory action.

Following resolution of comments, the RU will develop a Management Directive and Handbook that establish the administrative processes associated with back-fits. The development of the Management Directive and Handbook based on RL/REG-98-14 is anticipated to be complete by 12/31/98.

Disposition of any portion of C&R not accepted by the RU:

Not applicable.

**Present status of C&R:** The Management Directive and Handbook on Back-fit is scheduled for completion in December 1998.

# 3.3 Schedule Adjustments Mechanism Identification

**Comment and Recommendation:** "The RU review schedules are tied to DOE's contract milestones, exposing the RU to pressure to complete regulatory evaluations on a fixed schedule. Early in Part B, the RU should pursue, with the parties of the MOA, a mechanism that allows adjustments to the schedule if necessary for RU reasons."

**Designated RU Contact:**Robert C. Barr

**Disposition of C&R:**Not accepted.

**Disposition of any portion of C&R not accepted by the RU:** The changes presently incorporated in the revised Contract, including the J-Documents, acceptably resolve this concern. Involvement of the parties to the MOA is not necessary.

The RU has identified several potential causes that could result in exceeding the Contract required time for review of a deliverable. First, the Contractor submittal (deliverable) could be inadequate in scope or depth. For this cause, the Contract states, "This period may be extended if the information submitted by the Contractor is insufficient in scope or depth to facilitate the reviews ..." The Contractor incurs the potential financial liability associated with this type of delay. Second, the RU review of the Contractor submittal may result in open issues in which the Contractor is not effectively supporting resolution. For this cause the Contract states, "This period may be extended if ... open issue resolution is not effectively supported by the Contractor." The Contractor incurs the potential financial liability associated with this type of delay. Third, the RU review of the Contractor submittal may result in open issues in which the Contractor effectively supports resolution, but still necessitate an extension of the review; or fourth and last, the RU extends the review due to uncontrollable circumstances such as insufficient funding to attain necessary resources to complete submittal review on schedule as identified in the Contract. For these causes, Contract clause H.28, "Uncontrollable Circumstances," states, "in the event that an uncontrollable circumstance causes a material change in the ...schedule...subsequent to the completion of Part B of this Contract, an equitable adjustment of the Contract price to reflect such change in...schedule..., ... shall be granted..." The DOE incurs the potential financial liability associated with these types of delay.

Additionally, the RU has required changes to the Contract to provide reasonable assurance that review schedules will not be extended due to circumstances within the RU's control. During design, mandatory design reviews have been imposed on the Contractor. The RU will observe and provide comment on these reviews. Mandatory monthly topical meetings have been imposed on the Contractor to ensure timely resolution of issues identified during the Standards Approval Package reviews. Inspections will be conducted during design to assess Contractor compliance with the Safety Requirements Document, the Integrated Safety Management Plan and the Quality Assurance Implementation Plan.

The RU recognizes that safety issue resolution is of great importance and the highest priority. The RU completely understands the contractual mechanisms for review extension and has taken actions to revise the Contract to limit the probability of review schedule extension. The RU considers that the proposed revised Contract adequately protects both the DOE and the Contractor from delays in schedule caused by extension of reviews. Furthermore, for the successful advance of privatization, each involved entity must strive to resolve all issues, safety or non-safety, on the reasonable schedules established in the Contract. However, all involved entities must recognize that schedule and cost are secondary to safety.

**Present status of C&R:** The changes incorporated in the revised Contract, including the J-Documents, acceptably resolve this concern. Involvement of the parties to the MOA is not necessary. The RU considers this item closed pending verification by DOE-RL/PAD.

#### 3.4 Contract and Contract Attachment Inconsistencies

**Comment and Recommendation:** "There are inconsistencies among the contracts and the contract attachments. Early in Part B, the RU and Contracting Officer should improve their interface to ensure modifications affecting RU responsibilities are appropriately made."

#### **Designated RU Contact:**

Ronald J. Light

**Disposition of C&R:** With regard to inconsistencies within a contract and its attachments, the RU is presently making revisions to the "J" Documents. These changes are being checked for consistency -- to the extent practicable given the flux of contract negotiations -- against other parts of the Contract (and especially Section C, Statement of Work). Targeted completion is August 31, 1998.

Disposition of any portion of C&R not accepted by the RU: The finding of inconsistencies between the privatization contracts is rendered moot since only one Contractor has been selected to proceed into Part B. Moreover, the differences cited are not evidence of a lack of effective interface between the Regulatory Official (RO) and the Contracting Officer (CO), as is suggested. Instead, they are an outcome of a built-in concept of privatization. The BNFL negotiated proposal to defer submittal of some drafts and outlines was within its authority for tailoring of approach and within the discretionary authority of the RO, provided the timing of the changes did not interfere with the ability of the Contractor to achieve adequate safety and demonstrate the viability of proceeding to and performing in Part B. None of the differences between the two contractors' submission milestones were significant in the overall context of establishing and implementing an acceptable standards-based integrated safety management program. Discussions with the Contracting Officer confirm the RU belief that the interface between the RU and the CO is both effective and efficient.

**Present status of C&R:** Any apparent inconsistencies between the two contracts issued for Part A are not of concern in Part B since only one contractor will participate. Consistency with the balance of the single contract is being achieved by revisions to the "J-documents." The revisions are scheduled for completion in August 1998.

#### 3.5 Consistent PSAR Guidance Development

**Comment and Recommendation:** "The Contractors have selected different approaches to their PSARs. If two contractors are selected for Part B, the RU faces a challenge of developing consistent guidance for reviewing the two different PSARs. This guidance should be initiated early in Part B."

#### **Designated RU Contact:**

Lewis F. Miller, Jr.

**Disposition of C&R:** The RU agrees that guidance development should be initiated early in Part B. Preliminary planning for guidance development has begun.

The assessment team identified several specific items related to this issue. Each observation is discussed below.

Collateral Item #1: First, the RU should take action to require resolution of all BNFL standards and requirements issues in the early stages of Part B instead of waiting to resolve some issues prior to construction authorization.

*Response:* The RU agrees with this recommendation, and intends to resolve all BNFL standards and requirements issues within two months of the start of Part B.

Collateral Item #2: Another recommendation for developing the PSAR review guidance that was not provided in the review guidance for the Part A Contractor deliverables is to indicate review responsibilities (by discipline) and review interfaces within the various sections of the PSAR review guidance.

Response: The RU agrees with this recommendation, and will implement it in the review guidance.

**Disposition of any portion of C&R not accepted by the RU:** Only one contractor will be selected for Part B. This specific item is therefore moot.

Collateral Item 3: To ensure consistency in review guidance development in the conduct of reviews, the Team recommends that the RU specify the PSAR format and content guide to be used by both contractors versus allowing each contractor to select a PSAR format and content guide.

Response: The RU considers this recommendation moot, since there is only going to be one contractor.

However, the RU notes that BNFL, Inc. has not yet specified the format and content guide they intend to use, and considers this specification to be in the critical path for development of review guidance. Consequently, the RU has informed BNFL, Inc. that closure of this SRD open issue by submittal of an acceptable format and content guide is important.

**Present status of C&R:** Inconsistencies between the two contractor's approaches to PSAR preparation is no longer of concern since only one contractor has been selected to proceed with Part B. Preparation of guidance for the review of the contractor's PSAR has been initiated. The RU considers this item closed pending verification by DOE-RL/PAD.

#### 3.6 Pre-construction Inspection Procedures (Modules) Development

**Comment and Recommendation:** "Development of pre-construction inspection procedures (modules) should be elevated in priority. Resources should be allocated to ensure that inspection modules are available in sufficient time to train staff, advise stakeholders, and support all pre-construction and limited construction authorization inspection activities early in Part B."

#### **Designated RU Contact:**

Patrick P. Carier

**Disposition of C&R:** Pre-construction inspection procedures have been elevated in priority. The recent RU re-organization has focused resources on completion of this task. As a result, drafts of the required pre-construction inspection procedures have been developed and are in the process of being finalized. They are currently scheduled for completion by September 30, 1998. The current scope of the inspection procedures includes and is not limited to the following:

- Quality Assurance
- Design, Design Changes and Modifications
- Procurement Process
- Receipt Inspections
- Document Control
- Corrective Action Program
- Employee Concerns Program
- Assessment of Contractor Self-Assessment Capability

These procedures are being developed using existing NRC inspection modules and are being tailored to the needs of the RU. Completion of the needed inspection procedures will be accomplished in a phased approach. The initial set of procedures will be published in July 1998. Additional procedures will then be published monthly in August and September. Inspection procedures needed for the pre-construction phase of the project are therefore scheduled for completion by the end of the fiscal year. This schedule will allow sufficient time to advise stakeholders and support any pre-construction activities. The RU will have a just-in-time training program on these procedures consistent with its inspection program schedule.

## **Disposition of any portion of C&R not accepted by the RU:** Not applicable.

**Present status of C&R:** Preparation of required inspection procedures is in progress and on track to support pre-construction activities. The current schedule for completion is September 1998.

# 3.7 Clarification of RU Role in Land Lease

**Comment and Recommendation:** "The RU role in the land lease is unclear and should be clarified early in Part B. The RU should review the actual land lease, when it becomes available, to determine if any inappropriate transfers of RU obligations are apparent in the document."

# **Designated RU Contact:**

Ronald J. Light

**Disposition of C&R:** The Regulatory Unit has been actively involved in the development of the proposed Part B modifications to the BNFL contract. Although specific attention has been paid to Standard 4 and other contract clauses related to radiological, nuclear, and process safety regulation, the entire contract has been reviewed for possible impacts on the regulatory activities. Included in these reviews has been the land lease (Contract Attachment 7, U.S. Department of Energy TWRS Privatization Lease). The Regulatory Unit has determined, with the concurrence of the DOE-RL Deputy Chief Counsel, that no inappropriate transfers of RU obligations are apparent in the document, nor would they be binding. The latter is so because in the event of inconsistency between the terms of the lease and the terms of the Contract, the terms of the Contract shall take precedence. Further, no specific role for the Regulatory Unit with respect to the land lease has been identified.

As provided in the contract, the land lease will not be executed until after completion of the extended design phase of Part B (approximately 20 months after start of Part B). The Regulatory Unit will review any proposed changes to the lease prior to its execution between DOE "the customer" and BNFL.

Disposition of any portion of C&R not accepted by the RU:

Not applicable

**Present status of C&R:** The Regulatory Unit has reviewed the proposed Part B land lease and determined that it adequately addresses any concerns related to possible inappropriate transfers of Regulatory Unit obligations. Continuing review of any changes to the land lease in its execution form will be coordinated through the Contracting Officer to assure that they have no negative impacts to regulatory stability and predictability